

United States General Accounting Office Washington, D.C. 20548

Resources, Community, and Economic Development Division

B-266027

September 26, 1995

The Honorable Richard G. Lugar Chairman, Committee on Agriculture, Nutrition, and Forestry United States Senate

The Honorable Pat Roberts Chairman, Committee on Agriculture House of Representatives

Pesticide regulation is principally governed by the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA). This report provides a compendium of our work related to pesticide regulation and is intended to be a useful reference for the Congress, pertinent agencies, and other interested parties during deliberations on FIFRA's reauthorization and other legislative proposals.

Approximately 20,000 pesticide products containing about 600 active ingredients are registered on the market today. The agricultural sector accounts for 75 percent of the total volume of pesticides used. Pesticides are also used in many other places, such as hospitals, restaurants, and the home. While pesticides play an important role in food production and protection against insect-borne diseases, they also have the potential to create serious health and environmental problems. Because pesticides are designed to kill living organisms, unintended exposure can be destructive to the environment and the human populations exposed.

The Environmental Protection Agency (EPA) is responsible for balancing the risks to human health and the environment against the benefits of using pesticides. FIFRA requires EPA to register pesticides and regulate their uses so that they will have no unreasonable adverse effects on human health or the environment. By 1998, EPA is also required to reassess and reregister on the basis of current

GAO/RCED-95-272R, GAO Products Related to Pesticide Regulation

155289

scientific standards the thousands of pesticide products with active ingredients initially registered before November 1, 1984.

Because pesticides may remain on crops, FFDCA requires EPA to set tolerances—that is, the amount of a pesticide that can safely remain on or in an agricultural product or processed food. The Food and Drug Administration (FDA) and the U.S. Department of Agriculture, through their food inspection programs, monitor the residues of pesticides in foods and animal feed sold in interstate commerce.

Over the past 3 decades, GAO has issued numerous reports and testimonies examining various aspects of the federal government's efforts to regulate pesticides. Our work has focused on the following major topics:

- Pesticide Registration and Reregistration: Federal efforts to reassess pesticide safety began in 1972 when the Congress amended FIFRA to require EPA to reregister all pesticide products that were registered under older, less stringent standards for assessing a pesticide's long-term effects on health and the environment. Through August 31, 1995, EPA had made decisions on about 2,100 of the 18,200 pesticide products subject to reregistration. At current funding levels, EPA estimates that the earliest the reregistration program will be completed is 2005. Meanwhile, most of the thousands of pesticide products in use may continue to be sold and distributed even though knowledge of their health and environmental effects is incomplete. Our work in this area has focused on the progress and problems of the reregistration program.
- -- Warning of Pesticide Dangers: Because of EPA's slow progress toward reregistering pesticides, an early warning system to identify pesticides that pose unreasonable risks is critical. FIFRA's requirement that registrants submit information on a pesticide's unreasonable adverse effects is intended to provide such a warning by alerting EPA to an unsafe product. Our work in this area has focused on EPA's process for identifying, reviewing, and tracking studies on the adverse health and environmental effects of pesticides and on EPA's administration of FIFRA's provisions that allow the use of unregistered pesticides in an emergency without having to go through EPA's registration process.

- Groundwater and Watershed Contamination: About 40 percent of the total U.S. population and more than 90 percent of the country's rural population depend on groundwater for drinking water. Although concentrations of most of the pesticides detected in groundwater have been very low, little is known about the long-term health effects of low-level exposure to pesticides. Furthermore, pollutants from agricultural production, including pesticides, account for more than half of the pollutants entering U.S. lakes and rivers and potentially threatening wildlife and human health. Our work in this area has focused on EPA's strategy and efforts to protect the nation's surfacewater and groundwater from contamination by pesticides.
- -- Pesticide Residue Monitoring: Because of the extensive use of agricultural pesticides, residues on food need to be closely monitored to ensure a safe food supply. FDA selectively monitors foods on the basis of past experience with known or suspected misuse of pesticides. Our work in this area has focused on examining the extent to which marketed foods contain unsafe levels of pesticide residues and reviewing the effectiveness of federal efforts to monitor them.
- Banned and/or Unregistered Exported Pesticides:
  Banned and unregistered pesticides that are
  manufactured in the United States can be sold abroad.
  These pesticides may pose health and environmental
  risks in other countries and could be used on foods
  imported into the United States. Under FIFRA, EPA
  established a notification system to alert foreign
  governments and businesses about banned or
  unregistered pesticides that are sold abroad. Our
  work in this area has focused on the extent to which
  unregistered exported pesticides are found in imported
  foods and EPA's efforts to monitor the export of
  unregistered pesticides.
- -- Protection of Farmworkers: Because of the extensive use of pesticides in the agricultural sector, farmworkers are at particular risk from pesticide exposures. EPA estimates that the 3.5 million farmworkers suffer 5 times more sickness than other workers because of chronic exposure to pesticides. Our work in this area has focused on federal efforts to protect farmworkers from illnesses resulting from exposure to agricultural pesticides.

- -- Pesticide Data Management: To ensure that pesticides do not have any unreasonable adverse effects on the environment or human health, EPA and other federal agencies must rely on their monitoring activities and data from pesticide registrants. EPA and other agencies base risk assessments on such information as the toxicity of pesticide ingredients and the extent of human exposure. However, these data may not always be sufficient to assess pesticides' risks. Our work in this area has focused on problems associated with the efforts of EPA and other federal agencies to identify, collect, and manage key pesticide data.
- -- Setting Pesticide Residue Tolerances (Delaney Clause<sup>1</sup>):
  Because of differences between FIFRA and FFDCA, EPA
  applies different standards of risk in different
  situations and considers the benefits of using
  pesticides in some instances but not in others. In
  setting tolerances, EPA may allow the use of a cancercausing pesticide on raw foods or in certain processed
  foods when it has determined that the risk of cancer
  is negligible. However, under the Delaney Clause, EPA
  may not allow a cancer-causing pesticide in other
  processed foods no matter how minimal the risk. Our
  work in this area has focused on options for
  establishing a single standard for regulating the use
  of pesticides on foods.
- International Pesticide Standards: Although many countries set pesticide residue tolerances, the standards and the criteria on which they are based often differ. While equivalent standards among countries might facilitate trade, they might also weaken U.S. standards. Although other industrialized nations generally agree with U.S. requirements for assessing the effects of food-use pesticides on human health, there is less agreement on the required tests to measure the impact of pesticides on the environment and wildlife. Despite efforts by many countries to revise test requirements to bring them into greater harmony with U.S. standards for pesticide registration, many differences in evaluation

<sup>&</sup>lt;sup>1</sup>The Delaney Clause, included in section 409 of the FFDCA, states that no additive to processed foods will be considered safe if it is found to induce cancer when ingested by humans or animals.

<sup>4</sup> GAO/RCED-95-272R, GAO Products Related to Pesticide Regulation

procedures remain. Our work in this area has focused on identifying similarities and differences between the United States' and other countries' pesticide standards.

Nonagricultural and Lawn Care Pesticides: Pesticides used on lawns, public buildings, homes, and apartments may result in widespread human exposure. These pesticides can also end up in rivers, lakes, and groundwater through excessive and improper application and improper disposal of containers. EPA is concerned that such pesticides may persist in the environment, resulting in higher exposure than previously assumed. Concerns about the health effects of exposure to pesticides in nonagricultural applications have led to calls for improved notification of potentially affected populations when pesticides are applied by either commercial or household users. Our work in this area has focused on EPA's efforts to assess the health effects of lawn care pesticides.

Enclosure I includes a summary, organized by topic, of the background and findings of selected reports and testimonies issued within the past 10 years.

To identify major topics relating to pesticide regulation, we reviewed our past reports, testimonies, and other products, as well as issue briefs from the Congressional Research Service and other publicly available documents. To identify past work related to each major topic and obtain summaries of their background and findings, we used our document data base, which provided synopses of all of our past work on pesticides. From this database, we selected reports and testimonies that GAO issued within the past 10 years that are most relevant to each of the topics. The narrative portions in enclosure I may not reflect the current situations because they were prepared according to the circumstances existing at the time these products were issued. We conducted our work between August and September 1995.

We are sending this report to you because it pertains to activities under your Committees' jurisdiction. We are also sending copies of this report to the Senate and House Committees on Appropriations, the Senate Committee on Labor and Human Resources, the House Committee on Commerce, and the respective Senate and House committees having oversight responsibilities for pesticides and related food safety

matters. In addition, we are sending copies of the report to the Administrator of EPA; the Director, Office of Management and Budget; the Commissioner of the Food and Drug Administration; and the Secretaries of Health and Human Services and Agriculture. We will also make copies available to others upon request.

Please contact me at (202) 512-6111 if you or your staff have any questions. Major contributors to this report were Lawrence Dyckman, Associate Director; Susan Kladiva, Assistant Director; and Vincent P. Price, Evaluator-in-Charge.

Peter F. Guerrero

Director, Environmental Protection

Issues

Enclosure

# SYNOPSES OF GAO REPORTS AND TESTIMONIES RELATED TO REGULATORY ISSUES ON PESTICIDES

The material presented in this enclosure was derived from selected reports and testimonies that GAO issued within the past 10 years. The enclosure is not a comprehensive listing of all GAO products relating to a given subject but rather a judgmental selection of those products most relevant to each topic. The narrative portions may not reflect current situations because they were prepared according to circumstances at the time these products were issued.

#### PESTICIDE REGISTRATION/REREGISTRATION

<u>Pesticides: Reregistration Delays Jeopardize Success of Proposed</u> <u>Policy Reforms</u> (GAO/T-RCED-94-48, Oct. 29, 1993)

BACKGROUND: GAO's testimony on the Environmental Protection Agency's (EPA) reregistration of pesticides focused on the administration's proposal for reforming pesticide and food safety regulations.

FINDINGS: (1) EPA estimates that it will not complete pesticide reregistration until 2006; (2) EPA has only reregistered 250 of the 20,000 pesticides currently registered; (3) most of the reregistered pesticides' active ingredients are not high-priority food-use pesticides; (4) EPA failure to consider the complexity and magnitude of reregistration and the resources needed for the task has delayed the process; (5) 45 percent of the studies submitted to support reregistration have been unacceptable; (6) EPA will not be able to review all existing pesticide tolerances within 7 years; (7) the proposed reforms provide a sunset provision on pesticide

<sup>&</sup>lt;sup>1</sup>A "T" in a publication number indicates that the product is a testimony.

registrations and strengthen regulatory agencies' ability to enforce pesticide regulations; (8) EPA has not included all costs in its estimate of the additional funds needed to complete reregistration; (9) EPA is 4 years behind schedule for reregistering lawn care pesticides; and (10) the safety of lawn care pesticides may be uncertain even after reregistration, because EPA has not developed guidelines on their postapplication effects on human health.

<u>Pesticides: Pesticide Reregistration May Not Be Completed Until</u> 2006 (GAO/RCED-93-94, May 21, 1993)

BACKGROUND: GAO's review of EPA's reassessment and reregistration of older pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) focused on (1) EPA's progress in meeting the act's deadlines and (2) factors that have affected the registration program's completion.

FINDINGS: (1) EPA has only reregistered 31 pesticide products, but it has reassessed 2,400 products, most of which are on its highestpriority list; (2) EPA has only reviewed about 60 percent of the studies on the pesticides on its highest-priority list; (3) EPA estimates it will complete reregistration for all pesticides by 2003 or 2006, depending on funding; (4) the factors delaying reregistration beyond 1998 include the length and complexity of the reregistration process, inadequate program resources, and insufficient data to permit full reassessment of the pesticides; (5) EPA has substituted laboratory toxicity tests for field tests to reduce the length and complexity of the reregistration process; (6) EPA is studying the reasons for the high rejection rate for unacceptable pesticide studies, but it may not be able to reduce the rejection rate to the anticipated 10-percent level; (7) EPA did not discover until 1990 that more than one-half of the studies on

the highest-priority list lacked a substantial amount of required information and estimated that additional studies would take 2 to 4 years to complete; and (8) EPA had not met its projected schedules for reassessing pesticides on its highest-priority list because of incomplete information.

<u>Pesticides: Information Systems Improvements Essential for EPA's</u>
<u>Reregistration Efforts</u> (GAO/IMTEC-93-5, Nov. 23, 1992)

BACKGROUND: GAO's review of EPA's pesticide reregistration information systems focused on (1) how EPA uses automated information systems to track and analyze information for pesticide reregistration and (2) whether changes are needed to support its needs for pesticide reregistration information.

FINDINGS: (1) EPA has spent more than \$14 million to improve pesticide reregistration information systems; (2) EPA management problems include inadequate systems planning and poor data management; (3) because of an overload of reregistration information and time constraints, EPA adopted a rapid strategy to develop its new reregistration systems; (4) EPA developed new systems before it established program management and data requirements for the systems; (5) the lack of data management procedures jeopardized the consistency, accuracy, and completeness of information in the systems; (6) the lack of data definition standards made integrating and sharing information difficult; (7) the new systems did not meet users' needs for automated monitoring of pesticide information; and (8) compiling information about pesticides undergoing reregistration remained difficult, labor intensive, and time-consuming.

<u>Pesticides: USDA's Research to Support Registration of Pesticides</u> <u>for Minor Crops</u> (GAO/RCED-92-190BR, June 22, 1992)

BACKGROUND: GAO reviewed (1) the status of the research that the Interregional Research Project Number 4 coordinates to support the registration of pesticides for use on minor crops; (2) the uses the project makes of its resources; and (3) actions that the U.S. Department of Agriculture (USDA) has taken to ensure the availability of pesticides for use on minor crops after 1997.

FINDINGS: (1) Interregional Research Project Number 4 will not complete the research and analysis necessary to support the registration and reregistration of high-priority pesticides for use on minor crops by the 1997 deadline; (2) the research project situation arose because of past and present funding limitations; (3) because EPA and industry are involved in the registration process, increasing funding for the project would not ensure that pesticides are available for all minor crops; (4) growers could lose income through reductions in crop volume and quality, and consumers could see higher prices and lower quality; (5) project officials believe that their resources are used effectively because of the existing land grant university infrastructure, its research agenda, which includes those pesticides most likely to be approved by EPA, and annual reviews of its research priorities; and (6) USDA was slow to respond to the concern about the availability of pesticides for use on minor crops after 1997 and did not request funding to implement a plan to help ensure pesticide availability.

<u>Pesticides: USDA's Pesticides Residue Research Project</u> (GAO/T-RCED-92-38, Mar. 11, 1992)

BACKGROUND: GAO's testimony on USDA's role in the registration of pesticides for use on minor crops, focusing on: (1) the status of

USDA's Interregional Research Project Number 4, which supports EPA's pesticide registration process for minor crops; (2) how the research project uses its resources; and (3) USDA responses to the availability of pesticides for use on minor crops.

(1) FIFRA requires EPA to reassess and approve by 1997 FINDINGS: pesticides that had been registered before November 1984; (2) the research project will not complete the research necessary to support the registration of many high-priority pesticides for use on minor crops by the 1997 FIFRA deadline primarily because of funding limitations; (3) past and current project funding has not kept pace with the \$12 million estimate and averaged only about \$4.2 million annually since 1989; (4) project officials believe that they make effective use of limited resources, because they use the existing land grant university infrastructure, target the research agenda to include those pesticide uses that EPA is most likely to approve, and annually review research priorities; and (5) USDA has been slow to respond to the need for pesticides on minor crops, even though officials on the research project developed a strategic plan in 1989 to address such concerns.

<u>Pesticides: Reregistration and Tolerance Reassessment Remain</u>
<u>Incomplete for Most Pesticides</u> (GAO/T-RCED-89-40, May 15, 1989)

BACKGROUND: GAO testified on EPA's progress in reregistering pesticides and reassessing pesticide tolerances.

FINDINGS: (1) Despite some progress, EPA was still at a preliminary stage in assessing the risks of older pesticides; (2) EPA had not completely assessed any of the 822 pesticides subject to reregistration; (3) as of December 24, 1988, EPA had issued 194 preliminary assessments; and (4) EPA had completed tolerance reassessments for only 4 of the approximately 387 food-use

pesticides subject to reregistration and had completed all tolerance actions for 3 of those 4 pesticides. GAO also found that EPA needs to (1) establish procedures for reregistering individual products, (2) keep its final regulatory assessments current because of the dynamic nature of pesticide regulation, and (3) enforce label requirements imposed through interim registration standards.

### WARNING OF PESTICIDE DANGERS

<u>Pesticides: EPA Lacks Assurance That All Adverse Effects Data Have</u> <u>Been Reviewed</u> (GAO/T-RCED-92-16, Oct. 30, 1991)

BACKGROUND: GAO's testimony on EPA's process for identifying, reviewing, and tracking required studies on the adverse health and environmental effects of pesticides focused on whether (1) EPA knew the universe of studies it had received from registrants and (2) recent EPA initiatives to improve the processing of those studies would ensure that it could identify and review all such studies in a timely manner.

FINDINGS: (1) EPA may not have identified all studies on unreasonable adverse effects that it received from registrants; (2) recent procedural changes would not ensure that all studies submitted to EPA will be reviewed; (3) EPA's tracking system would not provide the level of assurance EPA's managers needed to be confident that the job is being done right; (4) EPA did not have a uniform rule concerning a registrant's written statement that certain studies of long-term health effects, ecological effects, and pesticides' behavior in the environment do or do not meet or exceed any applicable criteria; (5) while registrants may have complied with section 6(a)(2) of FIFRA by submitting data on the unreasonable adverse effects of pesticides before 1988 EPA had no means of readily identifying all of the data as section 6(a)(2)

submissions; and (6) the issuance of final regulations for implementing section 6(a)(2) to close the gaps that permit registrants to submit, but not specifically identify, data on unreasonable adverse effects would help ensure the timely identification and review of all such studies.

<u>Pesticides: EPA's Repeat Emergency Exemptions May Provide</u> <u>Potential for Abuse</u> (GAO/T-RCED-91-83, July 23, 1991)

BACKGROUND: GAO testified on EPA's administration of the emergency-use exemption provision of FIFRA, which allows states and federal agencies to use unregistered pesticides in an emergency without having to go through the EPA registration process.

(1) Since 1978, EPA has granted over 4,000 specific and FINDINGS: crisis exemptions for unregistered pesticides; (2) in fiscal year 1990, EPA granted almost 80 percent of the exemption requests for chemicals that had already received exemptions for that particular use and approved another 18 percent of the repeat requests by not revoking crisis exemptions; (3) by granting repeat exemptions, EPA may put companies that register pesticides at an economic disadvantage compared with companies that are able to sell their chemicals for uses that have not been registered; (4) because unregistered pesticides do not go through the EPA registration process, the extent of their effects on human health and the environment are unknown; and (5) the high number of repeat exemptions was due to a lack of criteria defining a complete registration application and nonspecific regulations precluding EPA from defining routine situations as emergencies.

# GROUNDWATER AND WATERSHED CONTAMINATION

Agriculture and the Environment: Information on and Characteristics of Selected Watershed Projects (GAO/RCED-95-218, June 29, 1995)

BACKGROUND: Recent federal, state, and local studies on water quality have identified agriculture as the United States' greatest source of nonpoint pollution—that is, pollution that cannot be traced to a specific point of origin. Agriculture contributes more than half the pollutants entering the nation's rivers and lakes. The threat to water quality posed by nonpoint sources of pollution has prompted renewed interest in watershed—based approaches to reducing pollution. GAO was asked to (1) determine the number, purpose, location, and funding of federal watershed projects that address pollution caused by agricultural production and (2) provide information on the lessons learned from selected innovative or successful watershed projects.

FINDINGS: Nationwide, 618 watershed-based projects aimed at agricultural sources of pollution were being planned or carried out through early 1995. The projects, ranging from as little as 5 acres to over 150 million acres in size, involved both surface water and groundwater resources and addressed a gamut of agricultural pollutants, such as animal waste, pesticides, and soil sediment. Through early 1995, these projects had received an estimated \$514 million in federal funds. Two key lessons learned were the need for (1) flexibility in the kinds of financial and technical assistance provided by federal agencies and (2) tailoring of approaches to local watershed management. Because watershed projects differ in characteristics—such as the type and source of pollutants, local agricultural practices, and the community's attitude—participants believed that a prescriptive, one—size—fits—

all approach would be inappropriate. At the local level, the projects' participants emphasized that the keys to reducing agricultural pollution include (1) building citizens' cooperation through education, (2) getting stakeholders to participate in developing the project's goals, and (3) tailoring the project's strategies, water quality monitoring, and regulatory enforcement efforts to local conditions.

<u>Pesticides: Issues Concerning Pesticides Used in the Great Lakes Watershed</u> (GAO/RCED-93-128, June 14, 1993)

BACKGROUND: GAO provided information on the amount and type of pesticides used in the Great Lakes watershed that focused on (1) whether pesticides contribute to toxic chemical levels in the Great Lakes, (2) pesticide storage and disposal in the Great Lakes region, and (3) whether the pesticides used are subject to EPA's pesticide reregistration program.

FINDINGS: (1) The federal government and private organizations lack sufficient database systems to track pesticide use in the Great Lakes' watershed; (2) out of an estimated 56 million pounds of pesticides used annually within the United States and Canadian Great Lakes watershed, 46 million pounds are used on agricultural crops and 10 million pounds are used on lawns and U.S. golf courses; (3) herbicides account for three-quarters of the total agricultural pesticides and are applied by aerial sprayers to control weeds; (4) fungicides and insecticides account for the remaining agricultural pesticides and are applied largely to fruits and vegetables to control diseases and pests; (5) persistent pesticides are retained in the Great Lakes for long periods because only 1 percent of the water in the Great Lakes is circulated annually, allowing pesticides to accumulate in sediments; (6) results from monitoring fish tissues show that restricted

pesticides are still being detected at high concentrations and may be more persistent than previously thought; (7) EPA needs to complete its program to monitor water quality and use current and accurate data in its pesticide reregistration program so that it can fulfill the requirements to monitor pesticides; and (8) although EPA has instituted a program to dispose of unusable pesticides in the Great Lakes watershed, large quantities of banned, spoiled, and improperly stored pesticides remain.

Groundwater Protection: Validity and Feasibility of EPA's
Differential Protection Strategy (GAO/PEMD-93-6, Dec. 9, 1992)

BACKGROUND: GAO evaluated the feasibility of protecting groundwater from pesticide contamination according to the relative vulnerability of various geographic areas.

FINDINGS: (1) There were significant gaps in the data needed to conduct valid vulnerability assessments; (2) half the states did not have data on the vadose<sup>2</sup> and confining zones; (3) existing information was generally not of sufficient geographic resolution to be useful in vulnerability assessments; (4) there was great variability across states in the availability and sufficiency of the data; (5) the most extensive tests of depth, recharge, aquifer, soil, topography, impact, and conductivity (DRASTIC) have found no positive relationship between DRASTIC scores and pesticide contamination; (6) a discriminant analysis approach to predict groundwater contamination was validated once and for only one pesticide; (7) none of the mathematical models were adequately

 $<sup>^{2}</sup>$ The vadose zone is the area in the earth's surface above the permanent groundwater level.

validated to justify their use for developing state management plans; and (8) states generally used unvalidated methods for their assessments and, in most cases, did not verify models' predictions with monitoring data.

Groundwater Protection: Measurement of Relative Vulnerability to Pesticide Contamination (GAO/PEMD-92-8, Oct. 31, 1991)

BACKGROUND: GAO evaluated the feasibility of differentially protecting groundwater from pesticide contamination according to the relative vulnerability of different geographic areas and focused on the degree to which (1) states and counties are uniform in their susceptibility to groundwater contamination and (2) two common measures of relative vulnerability diverge in identifying areas that are susceptible to contamination.

FINDINGS: (1) Although EPA has taken the position that the variation in statewide sensitivity to pesticide contamination of groundwater is too large for uniform management of pesticides at the state level, it has not taken a stand on how large the within-state areas to be managed differently should be; (2) because the variability in hydrogeologic vulnerability does not become significantly smaller when moving from the national level to the state and to the county levels, it generally makes no more sense to make distinctions among counties than it does to treat an entire state as a uniform area; (3) the lack of uniformity in vulnerability both between and within counties indicates that EPA risks undermining its differential protection philosophy if it permits states to differentially protect groundwater on the basis of county-level differences in vulnerability; (4) the system EPA endorses would target manifestly different areas for differential protection than a system that included data on population exposure; (5) techniques that provide valid vulnerability assessments at the

subcounty level are expensive when applied across an entire county; and (6) it is important for states to explicitly consider the number of groundwater users as a factor in developing differential pesticide management plans.

<u>Pesticides: Act Promptly to Minimize Contamination of Groundwater</u> <u>by Pesticides</u> (GAO/T-RCED-91-46, May 8, 1991)

BACKGROUND: GAO's testimony on EPA's efforts to minimize pesticide groundwater contamination focused on its (1) assessment of pesticides' leaching potential, (2) regulation of pesticides that may leach into groundwater, and (3) consideration of human exposure to pesticides in groundwater when setting and reviewing limits for pesticide residues in food.

FINDINGS: (1) EPA needed to take more initiative in ensuring the minimization of pesticide contamination; (2) because EPA was slow in reviewing scientific assessments of pesticides' potential to leach into groundwater, detailed information concerning leaching factors was unavailable to pesticide applicators; (3) EPA was slow in reassessing older pesticides; (4) while EPA sometimes used available regulatory measures, it could do more to help prevent further groundwater contamination; (5) because EPA's assessment of risks from pesticide-contaminated food did not routinely consider additional exposure that could result from pesticide-contaminated groundwater, EPA had not ensured that pesticide tolerances were set low enough to protect public health; and (6) although EPA planned to implement a new program assigning states a major role in managing pesticide use to minimize groundwater contamination, EPA will still have to continue regulatory actions, because the program will not encompass all potentially hazardous pesticides and because EPA did not anticipate implementing the program for several years.

<u>Pesticides: EPA Could Do More to Minimize Groundwater</u> Contamination (GAO/RCED-91-75, Apr. 29, 1991)

BACKGROUND: GAO examined EPA's efforts to (1) assess pesticides' leaching potential into groundwater, (2) regulate those pesticides that could leach into groundwater, and (3) consider human exposure to pesticides in groundwater when setting and reviewing limits for pesticide residues in food.

FINDINGS: (1) EPA made limited progress in assessing the leaching potential of the 16 pesticides it identified as groundwater contaminants in 1985; (2) 40 percent of EPA's studies on pesticides were unacceptable and may have to be redone, and it could be years before EPA has complete data to conduct comprehensive leaching assessments for those pesticides; (3) insufficient resources, staff shortages, low priorities, and ineffective policies addressing the potential for groundwater contamination have contributed to EPA's limited progress; (4) EPA's system for tracking data requirements and studies was unreliable; (5) EPA did not fully or consistently use the regulatory measures available to reduce groundwater contamination; (6) groundwater contamination was not among the specific criteria in the EPA regulation for initiating special reviews; (7) EPA plans to request that states develop management plans for pesticides that leach into groundwater; and (8) in setting and reviewing tolerances for pesticide residues in food, EPA did not routinely consider human exposure resulting from pesticides in groundwater.

Agriculture: USDA Needs to Better Focus Its Water Quality Responsibilities (GAO/RCED-90-162, July 23, 1990)

BACKGROUND: GAO reviewed USDA's management and coordination of water quality activities.

(1) USDA developed a water quality initiative for fiscal year 1990 to expand its ongoing water quality programs and establish new programs; (2) 10 USDA agencies are involved in water quality activities and plan to spend \$155 million this year; (3) USDA expects the initiative to be more comprehensive and better coordinated than its previous water quality activities; (4) groundwater contamination is a critical issue because groundwater is the major source of water for many Americans; (5) the agricultural sector is the largest user of pesticides and fertilizers, and these chemicals are increasingly being found in surface water and groundwater supplies; (6) the public increasingly perceives that farm chemicals found in groundwater threaten human health and that limiting their use is warranted; (7) USDA's Low-Input Sustainable Agriculture Program (LISA) offers research grants to promote agricultural production methods that reduce the use of agricultural chemicals and protect the environment; and (8) USDA has not developed a comprehensive departmental policy on water quality.

# PESTICIDE RESIDUE MONITORING

Pesticides: Reducing Exposure to Residues of Canceled Pesticides (GAO/RCED-95-23, Dec. 28, 1994)

BACKGROUND: GAO reviewed (1) whether marketed foods contain unsafe levels of residues from canceled pesticides and (2) EPA's procedures for revoking tolerances for canceled food-use pesticides.

FINDINGS: (1) EPA believes that most marketed foods do not contain unsafe levels of residues from canceled pesticides because most pesticides do not persist in the environment for very long; (2) residues from a particular class of canceled pesticides do persist,

particularly in fish, and pose a health risk to some consumers over their lifetimes; (3) in 1991, EPA proposed lower action levels for five canceled pesticides in fish to reflect the decline in actual residue levels; (4) the reduced action levels have not been implemented because FDA believes that EPA has not fully demonstrated the need for lower action levels; (5) many state monitoring programs would be affected by lower action levels because they use federal standards in issuing fish consumption advisories; (6) EPA has taken over 6 years to revoke tolerances for canceled pesticides; (7) the current process for revoking tolerances takes too long and inefficiently uses scare resources; (8) linking residue revocations to pesticide cancellations would be more efficient and would reduce consumers' exposure to pesticide residues in imported food; and (9) although EPA has made progress in revoking tolerances for canceled pesticides, its revocation backlog is expected to increase because of additional pesticide registration cancellations.

Food Safety: Fundamental Changes Needed to Improve
Monitoring of Unsafe Chemicals in Food (GAO/T-RCED-94-311,
Sept. 28, 1994)

BACKGROUND: GAO's testimony on the need to improve the effectiveness of the federal food safety system focused on (1) the USDA's National Residue Program (NRP) for monitoring chemical residues in meat and poultry and (2) the overall federal structure for controlling chemicals in all foods.

FINDINGS: (1) NRP has weaknesses in testing and sampling, as well as in the support it receives from regulatory agencies; (2) NRP's test results are not as useful as they should be; (3) other agencies provide limited support to NRP; (4) the fragmentation of responsibility across many agencies impedes the identification of

chemical risks; (5) problems in the legal and regulatory structure compromise efforts to reduce risk; (6) increased focus on prevention is a better approach to ensure food safety than end product testing; (7) federal enforcement efforts do not provide the backup that is necessary to ensure compliance with federal food safety standards when violations occur; and (8) the problems in the domestic food safety system are also relevant for imported foods because federal agencies have even less control over the production of imported foods.

Food Safety: USDA's Role Under the National Residue Program Should Be Reevaluated (GAO/RCED-94-158, Sept. 28, 1994)

BACKGROUND: GAO's review of USDA's National Residue Program focused on whether (1) the program can help ensure that the nation's meat and poultry supply is free of potentially hazardous chemical residues and (2) assistance from EPA and FDA is adequate to support NRP's needs.

FINDINGS: (1) NRP testing is not comprehensive and the methodology used to select food samples is flawed; (2) the Food Safety and Inspection Service (FSIS) does not know the extent to which potentially harmful residues may exist in the meat and poultry supply; (3) NRP generates questionable results concerning potentially hazardous residues in meat and poultry; (4) FSIS does not always have complete information on chemical residues or the potential hazard such residues may present to consumers; (5) although FDA is principally responsible for investigating residue violations referred by FSIS, resource constraints and legislative restrictions limit its ability to take enforcement action against violators; (6) a risk-based approach to residue prevention, detection, and control may better ensure the safety of meat and poultry than the current approach that relies on testing end

products; (7) FSIS recognizes the value of changing its testing approach and has begun to design new testing systems; (8) FSIS resources could be more effectively used if FSIS delegates responsibility for establishing and operating quality assurance systems to the industry; and (9) FSIS could selectively monitor the effectiveness of industry programs and assist industry by developing information on compounds in use and test methods.

Food Safety: Changes Needed to Minimize Unsafe Chemicals in Food (GAO/RCED-94-192, Sept. 26, 1994)

BACKGROUND: GAO's review of the federal government's efforts to monitor harmful chemical residues in food focused on the (1) methodologies and data used to identify chemical risks, (2) federal government's legal and regulatory structure, (3) federal government's enforcement processes, and (4) safety of imported foods.

FINDINGS: (1) Because of fragmented responsibility, federal efforts to assess the risks posed by chemicals are inconsistent and may produce questionable results; (2) the different standards and regulations governing the approval and use of chemicals in food could expose consumers to questionable risks; (3) federal enforcement mechanisms do not prevent contaminated food products from entering the food supply and do not effectively penalize violators or deter future violations; (4) ensuring the safety of agricultural products is often problematic because federal agencies have less control over imported foods; (5) although meat and poultry can be imported only from countries with equivalent inspection systems, no such requirement is in place for other types of food products; and (6) the federal government has limited assurance that many imported products have been adequately inspected in the country of origin.

<u>Pesticides: Status of FDA's Efforts to Improve Import Monitoring</u> and <u>Enforcement</u> (GAO/T-RCED-93-55, June 16, 1993)

BACKGROUND: GAO testified on FDA's improvements to its pesticide monitoring program.

(1) FDA plans to implement its automated Import Support and Information System (ISIS) in its Seattle district by September 1993; (2) FDA plans to have full ISIS implementation in its Pacific region by December 1994, but it has no specific plans for expanding ISIS nationally; (3) FDA has extensively revised plans for two system modules, but it has not established development and implementation plans for these modules as recommended; (4) FDA has made significant progress in interfacing ISIS with the Customs Service's Automated Commercial System (ACS), which has increased efficiency, reduced paperwork, and increased the flow of imports through ports; (5) FDA considers the ISIS-ACS interface an integral part of its baseline system because it reduces the burden of data on ISIS users; (6) deterrents against improper distributions of adulterated food imports are not effective because some importers choose to pay the relatively low damages rather than destroy or export their shipments; (7) FDA believes that basing civil damages on potential public health risks would be scientifically questionable and extremely costly because the risks are very small; (8) importers' disregard for FDA instructions to destroy or export adulterated food undermines FDA's monitoring program and is a longterm problem; and (9) improvements in FDA's monitoring program would detect more adulterated shipments with existing resources.

<u>Pesticides: Adulterated Imported Foods Are Reaching U.S. Grocery Shelves</u> (GAO/RCED-92-205, Sept. 24, 1992)

BACKGROUND: GAO's review on FDA's pesticide monitoring program focused on whether (1) federal deterrents are adequate to prevent pesticide-adulterated food from reaching U.S. grocery shelves and (2) FDA is using its resources to maximize detection of adulterated shipments.

FINDINGS: (1) FDA has increased its testing of shipments for pesticide residues despite the fact that its staffing has not kept pace with the increased volume of inspections; (2) shipments FDA refuse still reach U.S. markets because importers retain possession of suspect shipments; (3) FDA lacks the authority to enforce fines to importers for distributing adulterated food, and even when fines are paid, the monetary consequences to the importer are not heavy; (4) bond agreements between importers and the Customs Service are the main enforcement tool; (5) while liquidated damages are not intended to be a penalty for endangering public health and are not high enough, importers often can avoid, reduce, or postpone paying them; (6) the law provides only for criminal penalties, which are harder to obtain; (7) a few repeat offenders are responsible for the majority of violations and do not have to place their shipments in controlled storage; and (8) FDA could more effectively use its limited resources by controlling food shipments that are deemed more probable of violating regulations, restricting distribution of companion shipments of sampled shipments, and expediting the implementation of automatic detention on suspect importers.

Imported Meat and Livestock: Chemical Residue Detection and the Issue of Labeling (GAO/RCED-87-142, Sept. 30, 1987)

BACKGROUND: GAO reviewed the Food Safety and Inspection Service's program to detect chemical residues on imported meat and livestock.

(1) Although the Food Safety and Inspection Service (FSIS) developed an annual plan in 1986, which included 406 chemicals for consideration and 100 for testing, it lacked detailed, current information on the chemicals used abroad; (2) FSIS plans to require foreign countries that want to export meat to the United States to submit an annual residue testing plan to USDA; (3) because FSIS met its 1986 testing quotas by May 1, 1986, it did not test meat imported after that date for the full range of residues; (4) FSIS did not always remove from the U.S. food market the remainder of lots that showed chemical violations; (5) in 1986, about 60 percent of imported live animals came from Mexico, which since 1984 has been ineligible to export meat to the United States because of chemical residues; (6) FSIS does not have current information to adequately test for chemicals used in Mexico; and (7) mandating quality control reports and country-of-origin labeling of meat could increase food costs and could constitute a nontariff trade barrier.

<u>Pesticides: Need to Enhance FDA's Ability to Protect the Public From Illegal Residues</u> (GAO/RCED-87-7, Oct. 27, 1986)

BACKGROUND: GAO's review of FDA's activities to protect the public from exposure to illegal pesticide residues in the domestic food supply under the Food, Drug, and Cosmetic Act focused on FDA's (1) monitoring of the nation's domestic food supply for illegal residues and (2) efforts to prevent food containing illegal residues from reaching the market.

FINDINGS: Because FDA could not monitor all food that might contain illegal pesticide residues, it designed its monitoring program to selectively spot-check a very small amount of domestically produced food and remove food that it found to contain illegal residues. FDA's pesticide monitoring program has two major shortcomings because the agency does not (1) regularly test food for a large number of pesticides that might be present in food, including a number of pesticides that, according to FDA, require continuous or periodic monitoring because they are known as potential health hazards and are likely to be used; (2) prevent the marketing of most of the food that contains illegal pesticide residues; and (3) penalize growers who market food with illegal pesticide residues when FDA is unable to remove it from the market.

Pesticides: Better Sampling and Enforcement Needed on Imported Food (GAO/RCED-86-219, Sept. 26, 1986)

BACKGROUND: GAO reviewed FDA's efforts to protect the public from exposure to illegal pesticide residues in imported food.

FINDINGS: (1) FDA's pesticide monitoring program provides limited protection against public exposure to illegal residues in food; (2) FDA samples less than 1 percent of 1 million shipments of imported food annually; (3) FDA inspectors at various ports of entry decide the extent to which they apply sample criteria; and (4) although FDA uses five multiresidue tests that individually detect many pesticides on a single sample, FDA laboratories normally use only one method for each sample. GAO also found that (1) although FDA policy requires importers to all sampled shipments intact until FDA determines that the product is residue—free, FDA permits importers to release the majority of sampled shipments to U.S. markets before they spoil; (2) of 164 adulterated samples, 73 were not recovered before public consumption; and (3) there were only eight documented

cases in which FDA assessed damages on importers because adulterated food reached the marketplace.

#### BANNED/UNREGISTERED EXPORTED PESTICIDES

<u>Pesticides: Limited Testing Finds Few Exported Unregistered</u>

Pesticide Violations on Imported Food (GAO/RCED-94-1, Oct. 6, 1993)

BACKGROUND: GAO (1) identified unregistered pesticides produced in the United States for export and (2) determined, according to the results of FDA's and USDA's tests, whether these pesticides are returning to the United States as residues on imported food.

FINDINGS: (1) Of the 27 unregistered pesticides that U.S. manufacturers produce for export, 19 have never been registered and 8 have been fully or partially canceled; (2) limited testing has found few violations of residue tolerances; (3) Mexican produce has accounted for over 50 percent of the pesticide violations on imported foods; (4) FDA does not test all 27 pesticides because some pesticides are not likely to leave a residue, the United States imports little produce from the countries where the pesticides are used, or it is unaware of the pesticides' existence; (5) USDA has tested only 3 of the 27 pesticides because it lacks specific information on the health effects of the untested pesticide residues; (6) residues from unregistered pesticides may not come from U.S.-manufactured pesticides because some unregistered pesticides are manufactured in other countries; (7) FDA lacks sufficient information to identify all exported unregistered pesticides and their use; and (8) FDA does not have sufficient reference standards and testing methodologies to test all unregistered pesticides.

<u>Pesticides: Export of Unregistered Pesticides Is Not Adequately</u> <u>Monitored by EPA</u> (GAO/T-RCED-89-31, May 3, 1989)

BACKGROUND: GAO téstified on EPA's procedures for monitoring exports of unregistered pesticides and notifying foreign governments of U.S. actions taken on some pesticides.

FINDINGS: EPA (1) did not have a program for monitoring pesticide manufacturers' compliance with export notification requirements; (2) did not require export notices for unregistered pesticides that were similar to registered pesticides in composition and use; (3) lacked adequate procedures for preparing and issuing notices to foreign governments when it took significant action on a pesticide because of a serious health or environmental concern; and (4) had not updated a 1985 booklet that summarized and clarified its actions on canceled, suspended, and restricted pesticides.

<u>Pesticides: Export of Unregistered Pesticides Is Not Adequately</u> <u>Monitored by EPA</u> (GAO/RCED-89-128, Apr. 25, 1989)

BACKGROUND: GAO reviewed EPA's implementation of FIFRA provisions regarding pesticide notification requirements.

FINDINGS: (1) EPA lacked an effective program to monitor pesticide manufacturers' compliance with pesticide export notification requirements; (2) pesticide notices did not include sufficient and meaningful information for foreign governments to adequately identify pesticide products; (3) EPA's policy of exempting unregistered pesticide products because of their similarity and use hindered its efforts to monitor pesticide manufacturers' compliance with the notification requirements; (4) EPA received notices from about 26 percent of companies that exported 80 percent of unregistered pesticide products to the United States; (5) EPA

lacked internal procedures for preparing and issuing notices to foreign countries and international organizations regarding significant action on individual pesticides; and (6) an EPA booklet on canceled, suspended, or restricted pesticides was outdated, and foreign governments lacked current pesticide guidelines.

# PROTECTION OF FARMWORKERS

<u>Pesticides on Farms: Limited Capability Exists to Monitor</u>
Occupational Illnesses and Injuries (GAO/PEMD-94-6, Dec. 15, 1993)

BACKGROUND: GAO's review of federal and state efforts to monitor occupational illnesses resulting from exposure to pesticides on farms focused on whether federal and state monitoring systems provide sufficient information on pesticide-related illnesses in the farm sector.

FINDINGS: (1) Although numerous federal and state systems provide information on acute pesticide-related illnesses, none address delayed or chronic health effects, and all but one are limited in scope and information quality; (2) the national incidence of pesticide illnesses that occur in the farm sector could not be determined because of a lack of sufficient data and monitoring; (3) EPA is responsible for determining the potential occupational risks of pesticide use in the farm sector, developing practices to mitigate these effects, and establishing systems to monitor their effectiveness; (4) reporting of pesticide-related illnesses is inconsistent and incomplete because EPA relies on informal and voluntary state and local reporting systems and information obtained from national surveys and general data sources; (5) although 25 states have mandatory reporting requirements for occupational pesticide-related illnesses, most states report pesticide-illness information with general disease information; (6)

California's monitoring system is the most effective and comprehensive and provides detailed information on pesticide-related illnesses; and (7) pesticide illness underreporting continues to be a serious problem because farmworkers often do not recognize and report illnesses and health care providers are not adequately trained to identify and report pesticide-related illnesses.

Summary Information on Farmworkers (GAO/HRD-92-30R, Apr. 10, 1992)

BACKGROUND: GAO summarized its recent reports and testimonies related to migrant and seasonal farmworkers.

FINDINGS: (1) Federal programs that serve the general population or workers in general do not provide assistance to many farmworkers; (2) because of limited funds, federal programs that primarily serve farmworkers cannot provide assistance to all eligible farmworkers; (3) federal regulation of pesticides, workplace conditions, and child labor do not adequately protect farmworkers' health and well-being; (4) data on farmworkers are limited; (5) the supply of adequate farmworker housing falls far short of demand; and (6) agricultural employers frequently fail to pay wages for all hours worked, pay wages promptly, and pay minimum wage rates.

Hired Farmworkers: Health and Well-Being at Risk (GAO/HRD-92-46,
Feb. 14, 1992)

BACKGROUND: GAO provided information on the extent to which federal laws, regulations, and programs protect the health and well-being of hired farmworkers.

FINDINGS: (1) Federal laws and regulations do not ensure that hired farmworkers are given sufficient information about pesticide hazards; (2) according to EPA estimates, each year hired farmworkers suffer up to 300,000 acute illnesses and injuries from exposure to pesticides; (3) EPA standards for protecting hired farmworkers exposed to pesticides do not require that they be informed on the specific chemicals they are exposed to or the potential health effects of those pesticides; (4) federal regulations on field sanitation do not protect hired farmworkers on small farms, and the Department of Labor's 1990 national survey of migrant farmworkers showed that 31 percent worked in fields without drinking water, handwashing facilities, or toilets; (5) federal labor laws and child labor regulations allow children to work in agriculture at a younger age than in other industries; (6) children may be more susceptible than adults to the harmful effects of pesticides, and between 1979 and 1983, approximately 23,800 children and adolescents were injured on farms, 300 of them fatally; (7) most migrant farmworkers do not receive medical services from Medicaid or the Migrant Health Program because they are undocumented aliens or do not qualify for cash assistance programs; and (8) hired farmworkers are at greater risk than other workers to receive fewer Social Security benefits than they should because their employers do not report all of their earnings to the Social Security Administration.

#### PESTICIDE DATA MANAGEMENT

<u>Pesticides: EPA's Efforts to Collect and Take Action on Exposure</u> <u>Incident Data</u> (GAO/RCED-95-163, July 12, 1995)

BACKGROUND: GAO discussed whether EPA (1) collects information on exposure to or incidents arising from the use of nonagricultural pesticides in order to evaluate the extent of risk to human health,

(2) takes action when the information it receives on such incidents indicates potential health risks, and (3) receives sufficient information to assess whether unacceptable risks are occurring. While the review focused on exposure to nonagricultural pesticides, the discussion of EPA's monitoring activities also encompasses agricultural pesticides because the agency's current system for monitoring incidents of exposure includes both agricultural and nonagricultural pesticides.

FINDINGS: Since the 1970s, EPA has collected data on incidents of exposure to pesticides. Using these data, EPA has taken a number of measures to protect public health. Although the agency has been able to take some actions using the data collected on incidents, the reports it receives frequently contain insufficient information for the agency to determine whether the pesticide involved presents an unacceptable risk to human health. Such key data as whether the pesticide product was misused, what symptoms the victim exhibited, and how the exposure occurred are often missing from the information EPA receives. As a result, there is often no clear evidence of cause and effect and EPA has little or no basis to assess risk and determine whether new or revised regulatory measures are needed.

EPA has recognized the limitations of its data on incidents of exposure to pesticides and is undertaking measures to improve the collection and management of these data.

Food Safety: Difficulties in Assessing Pesticide Risks and Benefits (GAO/T-RCED-92-33, Feb. 26, 1992)

BACKGROUND: GAO's testimony on federal regulation of pesticides focused on risk and benefit assessment of pesticides used in or on food.

FINDINGS: (1) EPA, FDA, and USDA share responsibility for regulating pesticide use for food, screening out those pesticides that present unreasonable risk, and approving those that provide benefits; (2) methodology and data limitations create uncertainties in the assessment of pesticide risks and benefits; (3) gaps in the knowledge of pesticide risks and benefits contribute to the uncertainties; (4) EPA does not consistently acknowledge uncertainties inherent in its assessments; (5) federal food safety agencies lack a coordinated strategy for systematically identifying, collecting, and managing key data needed to reduce assessment uncertainties; (6) weak management of information resources and poor design of information systems adversely affects data accessibility, reliability, and utility; (7) agencies do not always verify the accuracy and integrity of pesticide risk and benefit data; and (8) controversial policy issues hampering pesticide regulation include differing legal requirements, application of differing risk standards, and EPA inability to establish policy or guidelines in several areas of risk management.

Food Safety: USDA Data Program Not Supporting Critical Pesticide Decisions (GAO/IMTEC-92-11, Jan. 31, 1992)

BACKGROUND: GAO reviewed USDA's Coordinated Pesticide Data Program to determine whether (1) the program produces the data needed to improve pesticide regulatory decisions and (2) USDA has an effective strategy to manage program data.

FINDINGS: (1) USDA launched the Coordinated Pesticide Data Program to provide better pesticide data that would benefit USDA, EPA, and FDA in their regulatory responsibilities; (2) the program's key objectives are to collect comprehensive, statistically valid, and scientifically based data on pesticide usage and residue and to provide EPA with data to use in making pesticide reregistration

decisions; (3) USDA plans to collect data on pesticide usage and residue for fruit and vegetable crops from several states; (4) USDA's surveys on pesticide usage are proceeding on schedule, and EPA and FDA have expressed satisfaction with the resulting data; (5) USDA's efforts to collect data on pesticide residues are behind schedule, have been significantly reduced in scope from original plans, and will not yield statistically reliable results; (6) USDA underestimated the complexities in planning and implementing activities and requirements for sampling methods, laboratory testing, and quality assurance; (7) USDA, EPA, and FDA lack an agreement on program direction and assessment; and (8) USDA has not developed a strategy to determine whether available computer resources can adequately process or disseminate the data collected, and system requirements remain largely undefined.

<u>Pesticides: EPA's Information Systems Provide Inadequate Support</u> <u>for Reregistration</u> (GAO/T-IMTEC-92-3, Oct. 30, 1991)

BACKGROUND: GAO testified on EPA's information systems for ensuring that data submissions from firms reregistering pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act are properly identified, tracked, and reviewed.

FINDINGS: (1) Information on all data submissions made by registrants is redundantly entered and edited in several different information systems; (2) because information submitted by registrants may be scattered across nine different, nonintegrated systems, EPA is unable to quickly compile a comprehensive and reliable picture of the review status of a particular pesticide; (3) manual records have to be compiled and verified because critical information about pesticide studies is not kept in automated systems; (4) to fully integrate its information systems, EPA needs to establish standards for electronic data exchange and

system interfaces, identify and eliminate data input and editing redundancies, and consolidate remaining individual systems; (5) tracking systems used by case review managers function as support for specific operations, rather than for management decisions, and make it difficult for EPA to respond to informational queries in a timely and effective manner; (6) current systems provide neither complete nor accessible information; and (7) rather than designing systems to provide timely and effective management support for a critical regulatory responsibility, EPA has narrowly focused on automating specific processes that simply track the movement of paper files.

<u>Pesticides: Food Consumption Data of Little Value to Estimate Some</u> <u>Exposures</u> (GAO/RCED-91-125, May 22, 1991)

BACKGROUND: GAO's review of the reliability of EPA's exposure estimates for safe pesticide levels and its reduced sample size focused on the adequacy of data from USDA's survey of food consumption from 1987 to 1988 for EPA to estimate maximum dietary exposure to pesticide residues in food.

FINDINGS: (1) Budget constraints reduced the sample size of the 1987 to 1988 survey by about one-third from the 30,770 individuals USDA had surveyed from 1977 to 1978; (2) survey limitations raised questions about its usefulness even for large subpopulations; (3) EPA did not participate in the 1987 to 1988 survey's sampling design; (4) EPA's ability to adequately base tolerance assessments on exposure estimates for the five smallest subpopulations may have been compromised because the sampling error for these groups ranged from nearly 70 to 175 percent of the estimate; (5) EPA did not determine precision levels for exposure estimates based on 1977 to

1978 survey's data; and (6) EPA based its tolerance decisions, in part, on exposure estimates that may have lacked the precision necessary for setting tolerances.

<u>Disinfectants: Concerns Over the Integrity of EPA's Data Bases</u> (GAO/RCED-90-232, Sept. 21, 1990)

BACKGROUND: GAO's review of EPA's pesticide and disinfectant data systems focused on (1) the Pesticide Product Information System (PPIS); (2) the Pesticide Document Management System (PDMS); and (3) the Federal Insecticide, Fungicide, and Rodenticide Act and the Toxic Substances Control Act Enforcement System (FATES).

FINDINGS: (1) Key data on disinfectants were inaccurate, incomplete, or missing; (2) PPIS had inaccurate data on the number of disinfectants registered to kill tuberculosis bacteria; (3) EPA did not know the extent to which the systems' data on pesiticides were inaccurate or incomplete but estimated that it could be in the 60-percent range; (4) EPA lacked adequate procedures to ensure that data were accurately coded and entered into the systems and to ensure that data remained current; (5) PDMS was missing some data on disinfectant efficacy studies that registrants submitted to EPA between January 1, 1985, and June 26, 1989; (6) FATES did not include production data for some disinfectants; (7) although EPA intended some of the elements in the systems to include the same data, there were some strong indications that they did not; (8) EPA did not consistently classify and code disinfectants in a way that completely distinguished them from other types of antimicrobial pesticides in the three systems; and (9) EPA plans to improve the systems that did not address data integrity.

## DELANEY CLAUSE

Food Safety: A Unified, Risk-Based Food Safety System Needed (GAO/T-RCED-94-223, May 25, 1994)

BACKGROUND: GAO testified on the need to improve the federal food safety system.

(1) The current food safety system impedes efforts to address existing and newly identified food safety risks because of inconsistent and inflexible oversight and enforcement authorities, inefficient use of resources, and ineffective coordination; (2) the government should create a single, independent food safety agency responsible for enforcing a uniform set of laws to resolve longstanding problems, dealing with emerging food safety issues, and ensuring a safe food supply; (3) although consolidating food safety activities under an existing department is more likely because of the problems in establishing a new, independent agency, consolidation has its own set of problems; (4) the reorganization should be based on the federal government's commitment to consumer protection, adequate resources devoted to that purpose, and the responsible agency's competent and aggressive administration of food safety laws; (5) food safety inspections should not be consolidated under the Department of Agriculture because of the potential conflict of interest with its responsibilities to promote agriculture; (6) the Food and Drug Administration does not have an organizational conflict of interest, but its increased regulatory responsibilities have outpaced its resources and authorities; and (7) the current food safety laws need to be revised to make them uniform, consistent, and based on risk.

<u>Pesticides: Options to Achieve a Single Regulatory Standard</u> (GAO/RCED-94-57, May 13, 1994)

BACKGROUND: This report discusses (1) the federal pesticide laws and the policies that EPA developed to implement them and (2) legislative options for establishing a single standard for regulating the use of pesticides on food.

FINDINGS: (1) Because of conflicting pesticide legislation, EPA often applies different standards of risk for carcinogenic pesticides in different situations and considers the benefits of using pesticides in some instances but not in others; (2) EPA allows the use of carcinogenic pesticides on raw foods and certain processed foods when it has determined that the risk of cancer is negligible; (3) EPA policies to reconcile the differences in the pesticide laws have been overruled in court; (4) EPA expects that the court's decision will prove costly for the agricultural and pesticide industries and for EPA regulatory resources; (5) modifying EPA administrative policies would not resolve the legal differences in pesticide legislation; and (6) the Congress could establish a single standard for carcinogenic pesticides by amending the existing laws.

Food Safety: A Unified, Risk-Based System Needed to Enhance Food Safety (GAO/T-RCED-94-71, Nov. 4, 1993)

BACKGROUND: GAO testified on the federal food safety system and whether it should be revised.

FINDINGS: (1) The existing food safety system costs \$1 billion annually and does not effectively protect the public from foodborne illnesses; (2) system development has been piecemeal in response to specific health threats from particular food products and has not

responded to changing health risks; (3) food safety improvements have been hampered by inflexible and outdated inspection methods, inconsistent oversight and enforcement authorities, inefficient use of resources, and ineffective coordination; (4) visual inspection methods do not detect microbial contamination in meat and poultry; (5) fundamental legislative and structural changes are needed to improve the food safety system because regulatory agencies operate under different regulatory approaches; (6) the creation of a single food safety agency responsible for administering a uniform set of laws is the most effective way to deal with long-standing problems and emerging food safety issues and to ensure a safe food supply; (7) a single regulatory agency will increase efficiency, consistently treat food products that pose similar health risks, target resources to areas of greatest need, and reduce costs; (8) the National Performance Review recommends that all food safety functions be transferred to the Food and Drug Administration; and (9) the success of a single regulatory agency will depend on a clear commitment to consumer protection, adequate resources, competent and aggressive administration of the law, and the absence of conflicting interests.

#### INTERNATIONAL PESTICIDE STANDARDS

<u>U.S.-Chilean Trade: Pesticide Standards and Concerns Regarding</u>
<u>Chilean Sanitary Rules</u> (GAO/GGD-94-198, Sept. 28, 1994)

BACKGROUND: GAO (1) compared U.S. and Chilean processes for registering pesticides, setting pesticide residue tolerances for food, and monitoring compliance with these tolerances; (2) reviewed whether Chilean sanitary rules restrict potential U.S. agricultural exports; (3) reviewed Chile's environmental regulatory structure; and (4) discussed pesticide risks from imported Chilean pine logs.

FINDINGS: (1) the United States and Chile have relatively open processes for setting pesticide standards; (2) the countries' different standards and procedures for registering pesticides have not impeded agricultural trade between the two countries; (3) the United States sets its pesticide residue tolerances independently, while Chile accepts international standards; (4) the United States routinely monitors all types of domestic and imported foods for pesticide residues, but Chile only routinely monitors certain domestic dairy products and samples for particular pesticide residues: (5) Chilean exporters have established extensive controls to ensure that their exports meet U.S. standards, and their violation rate is significantly lower than that of any other foreign country; (6) certain Chilean sanitary rules, or the lack thereof, could impede U.S. exports of some agricultural products; (7) Chile's process for establishing sanitary regulations is not always clear, and Chile lacks formal procedures that would facilitate U.S. access to Chilean markets; (8) U.S. officials are working with Chilean officials to resolve pesticide and sanitary issues in advance of formal negotiations on a free trade agreement between the two countries; and (9) efforts are under way to find a substitute for treatment of imported pine logs with methyl bromide, an ozone depleter that is being phased out.

<u>Pesticides: A Comparative Study of Industrialized Nations'</u> <u>Regulatory Systems</u> (GAO/PEMD-93-17, July 30, 1993)

BACKGROUND: GAO's comparison of the pesticide standards and regulations in nations belonging to the Organization for Economic Cooperation and Development (OECD) with those of the United States focused on the (1) types of experimental test data required to register pesticides used on foods; (2) organizational structures, risk assessment, and risk management procedures used to evaluate pesticides; and (3) enforcement of pesticide standards.

FINDINGS: (1) Although the pesticide standards and regulations of the OECD nations agree with U.S. requirements for assessing human health effects of pesticides used on foods, specific test methodologies vary: (2) there is less agreement among OECD nations and the United States on the tests required to measure the effect of pesticides on the environment and wildlife: (3) the European Economic Community (EEC) is revising its test requirements to bring them into greater harmony with U.S. pesticide registration standards; (4) several OECD nations are willing to accept test data generated according to OECD, EPA, and other international organization guidelines; (5) industry officials believe that OECD has harmonized data requirements, but requirements for data presentation differ; (6) the OECD nations' technical resources and organizational structures for evaluating test data vary widely and do not correlate with the quantity of pesticides used; (7) the United States and OECD nations use different evaluation procedures for health risk assessments; (8) many OECD nations review product efficacy data to reduce the quantity of pesticides used, whereas the United States relies on market forces to minimize pesticide use: (9) many OECD nations have initiated pesticide reregistration programs; (10) the pesticide monitoring in OECD nations tends to focus on the testing of imported foods, with less emphasis given to exported food and domestically grown and consumed foods; and (11) many OECD nations will accept other residue standards if no national standard exists.

<u>Pesticides: Comparison of U.S. and Mexican Pesticide Standards and Enforcement</u> (GAO/RCED-92-140, June 17, 1992)

BACKGROUND: GAO examined differences between U.S. and Mexican requirements to register pesticides, tolerance levels for pesticides used on foods, and enforcement efforts.

FINDINGS: (1) The United States and Mexico have similar requirements for pesticide registration and tolerance setting, but there are significant differences in tolerances for certain pesticides used on foods; (2) both countries require applicants for pesticide registration to provide extensive health and environmental information on pesticides produced for food uses; (3) Mexico subjects EPA-approved pesticides to less scrutiny, but sometimes requests additional data on pesticides to account for Mexican climatic conditions; (4) U.S. and Mexican officials have formed a working group to address pesticide tolerance differences and set priorities; (5) the working group is not addressing pesticides for which both countries have set tolerances at different levels for the same commodities; and (6) while FDA has established a special monitoring program for imported Mexican produce, Mexico has limited monitoring capabilities and relies primarily on the private sector to monitor pesticide residues.

<u>International Food Safety: Comparison of U.S. and Codex Pesticide</u> <u>Standards</u> (GAO/PEMD-91-22, Aug. 22, 1991)

BACKGROUND: GAO compared current U.S. and Codex Alimentarius Commission<sup>3</sup> pesticide standards to determine the potential implications of such differences for U.S. trade and food safety.

FINDINGS: (1) Key areas in which differences existed between the Codex and U.S. processes for establishing pesticide standards include the mix of pesticides in each system, the use of good agricultural practices, pesticide and commodity definitions, data availability and interpretation, treatment of carcinogenic

<sup>&</sup>lt;sup>3</sup>The Codex Alimentarius Commission is a multinational organization established in 1962 under the auspices of the United Nations. The Codex has established standards, codes of practice, and guidelines for different foods and for food quality and safety concerns, including pesticide uses.

pesticides, and the use of dietary risk exposure assessments; (2) the Codex system includes about 170 pesticides and, when commodity groupings are converted to individual commodities, over 3,300 pesticide-by-commodity maximum residue limits (MRL), compared with over 400 pesticides and 8,500 pesticide-by-commodity MRL in the U.S. system; (3) MRL cannot be directly compared in about two-thirds of the Codex cases because the United States either has no standard or standards are defined differently: (4) less than half of the one-third of the pesticide-by-commodity combinations that can be compared are numerically the same; (5) among pesticides that EPA rated as possible carcinogens, the United States had lower MRL in 55 percent of the cases; (6) differences between U.S. and Codex MRL for major U.S. agricultural exports and imports showed that the United States had lower MRL for about 20 percent and Codex for 37 percent of the pesticide-by-commodity combinations; (7) the potential for restrictions on exports and imports and greater consumer exposure to pesticide residues will remain as long as differences in pesticide standards exist; and (8) the United States needs to systematically review and assess existing pesticide-by-commodity standards to determine if improvements can occur.

<u>Pesticides:</u> Five Latin American Countries' Controls Over the <u>Registration and Use of Pesticides</u> (GAO/T-RCED-90-57, Mar. 28, 1990)

BACKGROUND: GAO testified on five foreign governments' regulatory controls over the registration and use of pesticides.

FINDINGS: (1) Each of the five countries had laws and regulations controlling pesticide availability and use; (2) government monitoring and enforcement activities in all of the countries except one were generally limited; and (3) resource constraints

limited the governments' ability to obtain information on U.S. pesticide requirements and disseminate it to export growers. GAO also found that each country (1) prohibited registration for pesticides that EPA canceled or suspended; (2) required registrants to submit a certificate of free sale from the country of origin stating that the pesticide was legal for use; (3) used international maximum residue limits to establish the amount of acceptable pesticide residue on foods; (4) provided for reregistration reviews and procedures to revoke registration when adverse health, safety, or environmental factors became known; and (5) experienced no-tolerance violations on produce exported to the United States because U.S. tolerances had not been established for those specific crops.

#### NONAGRICULTURAL AND LAWN CARE PESTICIDES

Lawn Care Pesticides: Reregistration Falls Further Behind and Exposure Effects Are Uncertain (GAO/RCED-93-80, Apr. 6, 1993)

BACKGROUND: GAO's review of EPA's reregistration of major lawn care pesticides focused on (1) EPA guidelines for health risk assessments and (2) whether EPA classified any of the pesticides as carcinogens that could leach into the groundwater.

FINDINGS: (1) Studies on 18 major lawn care pesticides have been delayed up to 4 years; (2) EPA has reregistered some pesticides without waiting for study results; (3) EPA has evaluated 33 percent of the pesticides for their health or environmental risks; (4) EPA is considering suspending the use of one pesticide because of study delays and its suspected cancer risk; (5) EPA has suspended use of another pesticide because of its high toxicity to birds and aquatic species and is reviewing its suspected neurotoxicity to humans and its ability to leach into groundwater; (6) EPA does not have

specific lawn use testing and assessment guidelines, but plans to have final guidelines by 1997; (7) EPA has identified some potential human health problems and environmental effects, including leaching, but the pesticides' toxic effects are uncertain; and (8) EPA identified four pesticides as potential carcinogens.

Lawn Care Pesticides: EPA Needs to Assess State Notification Programs (GAO/RCED-91-208, Sept. 25, 1991)

BACKGROUND: GAO provided information on the types of notices the public receives when commercial applicators use pesticides.

(1) State notification requirements vary in terms of who FINDINGS: should be provided with information, when the information should be provided, what information should be provided, and whether the information must be requested: (2) 23 states require companies to provide notification when applying lawn care pesticides on residential sites, and as of April 1991, 6 additional states were considering requiring notification; (3) the primary notification methods include direct notification to customers, direct notification to neighbors upon request, and the posting of warning signs on treated lawns; (4) none of the 23 states that required notification had formally assessed the notification requirements' effectiveness; (5) EPA said that it was aware of state notification programs but lacked sufficient information to determine the programs' effectiveness; and (6) a lawn care industry trade organization supported states' efforts to require notification of pesticide applications.

<u>Pesticides: EPA and State Efforts to Ensure Safe Use of Lawn Care</u> <u>Pesticides</u> (GAO/T-RCED-91-50, May 9, 1991)

BACKGROUND: GAO testified on (1) EPA's progress in reassessing the health risks of widely used lawn-care pesticides and (2) the notification policy the lawn-care industry extends to its customers and others regarding the commercial application of pesticides to residential lawns.

FINDINGS: (1) Approximately half the states required companies to provide some form of notification when applying pesticides to residential lawns; (2) lawn-care companies served nearly 12 percent of single-family households; (3) EPA did not require commercial firms to provide any type of public notification when treating residential lawns; (4) the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1988 require EPA to evaluate the risks and benefits of a proposed pesticide before it is registered for use and to reregister older pesticides to bring them into compliance with current data requirements and scientific standards; (5) EPA's reregistration process is falling behind schedule by about 32 percent; (6) the 17 states that provided for advance notification of customers and neighbors frequently placed the burden of obtaining such notification on customers; and (7) notification requirements, among states that have implemented notification programs, varied to a considerable degree in terms of whom should be provided information, when the information should be provided, and what information should be provided.

Lawn Care Pesticides: Risks Remain Uncertain While Prohibited
Safety Claims Continue (GAO/RCED-90-134, Mar. 23, 1990)

BACKGROUND: GAO reviewed (1) the information that manufacturers, distributors, and professional applicators of lawn-care pesticides

provided to the public about product safety; (2) federal enforcement actions taken against unacceptable advertising claims; and (3) the reregistration status of 34 widely used lawn-care pesticides.

(1) The lawn care pesticides industry made safety claims about prohibited products that differed substantially from claims EPA allowed as part of product registration; (2) EPA cited limited resources and its focus on product misuse as reasons for assigning a lower enforcement priority to such false and misleading claims; (3) EPA lacked an effective program to monitor pesticide manufacturers' and distributors' compliance with registration requirements; (4) although the Federal Trade Commission (FTC) had authority to act against false and misleading advertising on safety, it preferred to defer to EPA in these matters because of its expertise and legislative authority; (5) FTC believed that EPA was informally handling advertising concerning the safety of professional applicators, although EPA lacked authority to do so; (6) EPA remained at a preliminary stage in reassessing the risks of lawn-care pesticides under its registration program; and (7) EPA had not completely reassessed any of the 32 older lawn-care pesticides that were subject to reregistration.

(150312)

# **Ordering Information**

The first copy of each GAO report and testimony is free. Additional copies are \$2 each. Orders should be sent to the following address, accompanied by a check or money order made out to the Superintendent of Documents, when necessary. Orders for 100 or more copies to be mailed to a single address are discounted 25 percent.

### Orders by mail:

U.S. General Accounting Office P.O. Box 6015 Gaithersburg, MD 20884-6015

or visit:

Room 1100 700 4th St. NW (corner of 4th and G Sts. NW) U.S. General Accounting Office Washington, DC

Orders may also be placed by calling (202) 512-6000 or by using fax number (301) 258-4066, or TDD (301) 413-0006.

Each day, GAO issues a list of newly available reports and testimony. To receive facsimile copies of the daily list or any list from the past 30 days, please call (301) 258-4097 using a touchtone phone. A recorded menu will provide information on how to obtain these lists.

For information on how to access GAO reports on the INTERNET, send an e-mail message with "info" in the body to:

info@www.gao.gov

United States General Accounting Office Washington, D.C. 20548-0001

Bulk Rate Postage & Fees Paid GAO Permit No. G100

Official Business Penalty for Private Use \$300

**Address Correction Requested**